

REMARKS

Summary of Office Action

Claims 1-18 were pending in this application.

The Examiner rejected claims 1-6 and 8-18 under 35 U.S.C. § 102(b) as being anticipated by Justis et al. U.S. Patent Application Publication No. 2002/0013586 (hereinafter "Justis").

The Examiner rejected claims 1 and 7 under 35 U.S.C. § 102(b) as being anticipated by Sekiguchi et al. U.S. Patent No. 5,482,029 (hereinafter "Sekiguchi").

Claims 10 and 18 were rejected under 35 U.S.C. § 112, second paragraph, for antecedence problems.

And the Examiner objected to the specification because of its arrangement. In particular, section headings were missing.

Summary of Applicants' Reply

Applicants have amended the claims to conform to U.S. patent practice and have added new dependent claims 19-23. Claims 10 and 18 have been amended to correct the antecedence problems, and the specification has been amended to include section headings and to correct other informalities.

No new matter has been added.

Reconsideration of this application in view of the amendments and following remarks is respectfully requested.

Rejections of Claims 1-6 and 8-18 Under 35 U.S.C. §102(b)

Claims 1-6 and 8-18 were rejected under 35 U.S.C. § 102(b) as being anticipated by Justis.

These rejections are respectfully traversed.

Justis discloses a spinal stabilization device at least partially formed of a shape memory material that “is capable of being deformed from an initial ‘memorized’ shape or configuration to a different shape or configuration, and then reformed back toward its initial shape or configuration” (Justis paragraph 33, lines 3-6; emphasis added).

In particular, Justis discloses “a central portion 30 of plate 22 … [that] has an initial or ‘memorized’ shape or configuration (see FIG. 4a), and a different shape or configuration (FIG. 4b) when deformed through the imposition of stress onto plate 22. [T]he central portion 30 will automatically recover toward its initial shape or configuration when the stress is removed from plate 22” (Justis paragraph 36, lines 1-9; emphasis added). The stress is “caused by relative movement between the upper and lower vertebrae” (*id.* at lines 14-15).

This is not applicants’ invention, which, in contrast, includes a longitudinal support that “can be permanently deformed with a prespecified force, which is greater than the peak forces encountered anatomically This deformation is carried out apart from implantation, and is carried out ... by the surgeon” (applicants’ specification, page 16, lines 9-14; emphasis added).

Moreover, the “longitudinal support is ... flexible while in each of the two stable shape states” (applicants’ specification, page 5, lines 29-30; emphasis added). That is, “[w]hile in [an] implantation state, ... the longitudinal supports 11 are intended to be flexible within

prespecified limits This achieves a dynamic stabilization of a predetermined spinal segment” (*id.* at page 15, lines 3-7).

Thus, during surgery, a surgeon can advantageously bend and deform a longitudinal support of the invention into a second stable shape customized to the anatomical needs of a patient before implantation of the support. Once implanted, “stabilization of a spinal-column section … is … carried out in such a way that flexibility is available … in the context of flexion and extension” (applicants’ specification, page 16, lines 1-5).

Accordingly, independent claim 1 requires a longitudinal support that is “plastically deformable from a first stable shape state into a second stable shape state by application of a prespecified bending force, the longitudinal support remaining flexible within predetermined limits while in the first and second stable shape states” (emphasis added).

Justis does not disclose or suggest applicants’ invention as defined in independent claim 1. In particular, Justis does not disclose that its central portion 30 is deformable from a first stable shape state into a second stable shape state. To the contrary, any second shape state of central portion 30 returns to the first or original shape state upon removal of the stress that caused the shape change in the first place – thus, the second shape state is not stable. Applicants’ second shape state is permanent and does not depend on the continued application of the bending force to maintain that second shape state.

Independent claim 1 is therefore not anticipated by Justis and should be allowable.

For at least these reasons, dependent claims 2-6 and 8-18, which depend directly or indirectly from independent claim 1, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

Moreover, for example, dependent claim 8 requires that the longitudinal support comprise a plastically deformable metal core encased in a human-tissue-compatible plastic. Although Justis discloses that there is a “wide variety of shape-memory materials … including … metal alloys … and shape memory polymers” (Justis paragraph 35, lines 1-5), and that “central portion 30 … be at least partially formed of shape-memory material” (*id.* at paragraph 32, lines 21-22), no where does Justis disclose or suggest a longitudinal support having a metal core encased in plastic. Thus, Justis also does not anticipate claim 8 for these reasons.

Accordingly, applicants respectfully request that the rejections of claims 1-6 and 8-18 under 35 U.S.C. §102(b) be withdrawn.

Rejections of Claims 1 and 7 Under 35 U.S.C. §102(b)

Claims 1 and 7 were rejected under 35 U.S.C. § 102(b) as being anticipated by Sekiguchi.

These rejections are respectfully traversed.

The Examiner said that Sekiguchi discloses “apparatus for the dynamic stabilization of bones or bone fragments, in particular spinal vertebrae, with a least one longitudinal support (FIG. 24, ref 401) that can be fixed to the vertebrae” (September 1, 2006 Office Action, page 7).

Applicants respectfully disagree.

Sekiguchi is directed to an endoscope system that has nothing to do with the dynamic stabilization of bones, bone fragments, or spinal vertebrae.

Sekiguchi's FIG. 24, cited by the Examiner, shows an "embodiment of the flexible pipe of the endoscope system" (Sekiguchi column 4, lines 2-3).

The flexible pipe of FIG. 24, as well as the other embodiments of flexible pipe disclosed by Sekiguchi, are intended to be "inserted from the anus to the S-shaped colon C of the large intestine" (Sekiguchi column 7, lines 24-25).

The flexible pipes are constructed with wires or helical pipes made of a shape memory alloy "connected ... to constant current sources ... housed in [a] main frame unit" (Sekiguchi column 6, lines 65-66).

Electric current passed through the shape memory alloy modifies the pipes' flexibility purportedly to allow the pipes to be inserted more deeply into the colon.

Accordingly, applicants submit that, contrary to the Examiner's assertion, the flexible pipes of Sekiguchi are not suitable for use in apparatus for the dynamic stabilization of bones, bone fragments, or spinal vertebrae, and more particularly, are not structurally suitable (especially with their electrical connections, for example) for being fixed to the vertebrae as required by applicants' claim 1.

Moreover, flexible pipes of endoscope systems in general are not known to be interchangeable with longitudinal supports of apparatus for the dynamic stabilization of bones, bone fragments, or spinal vertebrae. If the Examiner maintains such an assertion, applicants'

respectfully request that the Examiner cite a reference or other evidence in support thereof (*see MPEP § 2144.03(C)*).

Plainly, Sekiguchi does not disclose or suggest in any way applicants' apparatus for the dynamic stabilization of bones or bone fragments, and in particular, does not disclose or suggest applicants' longitudinal support.

Independent claim 1 is therefore not anticipated by Sekiguchi and should be allowable.

For at least these reasons, dependent claim 7, which depends directly from independent claim 1, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

Accordingly, applicants respectfully request that the rejections of claims 1 and 7 under 35 U.S.C. §102(b) be withdrawn.

New Dependent Claims 19-23

New dependent claims 19-23 have been added. These claims should be allowable for the same reasons as independent claim 1, from which they directly or indirectly depend.

Conclusion

The foregoing demonstrates that claims 1-23 are allowable. This application is

Application No. 10/542,646
November 28, 2006 Reply To Office Action

therefore in condition for allowance. Reconsideration and allowance are accordingly respectfully requested.

Respectfully submitted,



Garry J. Tuma
Registration No. 40,210
Attorney for Applicants

JONES DAY
Customer No. 51832
222 East 41st Street
New York, New York 10017
(212) 326-3939